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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/468,147	12/21/1999	GEORGE G. SCHLAUDER	6232.US.PI	3281

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[REDACTED]
EXAMINER

BRUMBACK, BRENDA G

ART UNIT	PAPER NUMBER
1642	[REDACTED]

DATE MAILED: 03/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/468,147	SCHLAUDER ET AL.
	Examiner	Art Unit
	Brenda G. Brumback	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 24 January 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6,12-15 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6,12-15 and 24-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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DETAILED ACTION

Continued Prosecution Application

1. The request filed on 01/24/2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/468,147 is acceptable and a CPA has been established. An action on the CPA follows.

The Preliminary Amendment filed 12/21/1999 is acknowledged. Claims 7-11, 16-23, and 27-43 were canceled. Claims 1-6, 12-15, and 24-26 are pending and under examination on the merits.

Drawings

2. Receipt of the formal drawings filed 09/24/2001 is acknowledged. See attached Notice of Draftsperson's Patent Drawing Review (PTO-948).

Priority

3. As was set forth in the prior Office action (Paper # 10), a review of the priority documents shows support for the US-type or US-subtype of hepatitis E virus (HEV) in the disclosure of Provisional Application 60/061,199 filed 10/15/1997. Support for SEQ ID NO:91 was not found in the provisional application, but was found in parent application 09/173,141. Therefore, for purposes of examination, the priority date for claims 1-5, 13-14, and 24-26 drawn to a US-type or US-subtype of HEV has been determined to be 10/15/1997 and the priority date for claims 6, 12, and 15, drawn specifically to SEQ ID NO:91, has been determined to be 10/15/1998.

Claim Rejections - 35 USC § 112

4. Claims 1-6, 12-15, and 24-26 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The instant claims recite a US-type hepatitis E virus (HEV) or a naturally occurring variant thereof. While the specification discloses naturally occurring variants of the polypeptides defined by SEQ

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ID NO: 91, 92, and 93 in terms of percent identity (see page 21, line 20, through page 22, line 2), the specification fails to teach the metes and bounds of a naturally occurring variant of the HEV virus itself. Absent such disclosure, the metes and bounds of the claimed invention cannot be ascertained and the claims are indefinite.

Claim 26 appears to be of improper dependency, as claim 41 from which claim 26 depends, does not recite a mammalian cell line. For purposes of examination, claim 26 has been interpreted as depending from claim 25. Correction is required.

5. Claims 1-6 and 24 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977) and have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for the following reasons:

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The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV or a naturally occurring variant thereof in a test sample comprising contacting the sample with a binding partner that binds specifically to a marker for the virus, wherein the marker is an antibody.

The state of the prior art and the predictability or lack thereof in the art: The art teaches that specific antibodies are produced in response to infection with or exposure to a virus. The art teaches that while detection of specific antibodies directed against a particular virus in a sample is indicative of present or past exposure to or infection with that virus, specific antibody is not in and of itself a marker for the actual presence of the virus in that particular sample (see Ray et al., pages 1218-1226, in Clinical Diagnosis & Management by Laboratory Methods, Henry, J.B. ed., W.B. Saunders Company, Philadelphia, especially pages 1225-1226, Serodiagnosis). Furthermore, the art teaches that variant strains of a virus may or may not elicit production of antibodies of the same immunoreactivity.

The amount of direction or guidance present and the presence or absence of working examples: The disclosure teaches detection of antibodies to HEV and teaches that the presence of antibodies in the serum is indicative of HEV infection or exposure (see page 84, lines 1-5, and page 102, lines 1-2). The specification does not teach that detection of specific antibody is indicative of the actual presence of the virus in that particular test sample. There are no working examples demonstrating a correlation between antibody detection and viral presence in a particular test sample. Furthermore, the disclosure fails to teach any naturally occurring variants of US-type HEV and fails to teach whether these variants would be expected to elicit antibodies with the same reactivity as the original virus.

The breadth of the claims and the quantity of experimentation needed: Because the claims are drawn to a method of detecting the presence of US-type HEV or a naturally occurring variant thereof in a test sample comprising detection of an antibody as a marker, and because the art teaches that 1) there is no correlation between antibody detection and viral presence in a test sample and 2) that variants of a

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virus may or may not elicit antibodies with the same immunoreactivity, it would require undue experimentation by one of skill in the art to be able to practice the claimed invention.

6. Claims 1 and 12-15 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of the presence of a US-type HEV in a test sample selected from stool, bile and liver cells, does not reasonably provide enablement for detection of the presence of a US-type HEV in other types of samples, such as serum and blood samples, for example. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV in a test sample comprising contacting the sample with a binding partner that binds specifically to a marker for the virus, wherein the marker is a virus specific polypeptide chain (antigen). The specification discloses the test sample of the present invention as encompassing serum, plasma, blood, saliva, sputum, semen, urine, feces, bile, spinal fluid, and tissue samples, among others (see page 15, lines 2-10).

The state of the prior art and the predictability or lack thereof in the art: While the art teaches that antibodies to HEV are detectable in serum or plasma samples, the art teaches that virus particles and/or viral antigens are detectable only in stool specimens, in bile of infected animals, and in liver tissue (see Krawczynski, K. Hepatology 17(5):932-941, 1993, of record in Paper # 3, especially page 933, last paragraph of the page, and page 834, first paragraph). The art does not teach that viral particles and antigens are detectable in samples such as blood, serum, plasma, sputum, semen, urine, and spinal fluid.

The amount of direction or guidance present and the presence or absence of working examples: The specification discloses and provides working examples for detection of antibodies directed against US-type HEV and detection of US-type HEV RNA in serum samples; it does not disclose methods for

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detection of US-type HEV virus, polypeptides of the virus, or antigens of the virus in any type of test sample. There are no working examples describing detection of US-type HEV particles in any test sample.

The breadth of the claims and the quantity of experimentation needed: Given the teachings in the art that HEV particles and/or antigens are detectable only in specific types of samples and absent any disclosure in the present specification as to how to detect US-type HEV particles and/or antigens in other types of samples, one of skill in the art would be unable to practice the claimed invention commensurate in scope with the claims.

7. Claims 25 and 26 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detection of a US-type HEV in a hepatocyte culture system, does not reasonably provide enablement for detection of US-type HEV in other mammalian cell lines or in human fetal kidney cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The nature of the invention: The claimed invention is drawn to a method of detecting the presence of a US-type HEV in a test sample, comprising contacting the sample with a binding partner that binds specifically to a marker for the virus, wherein the test sample is a mammalian cell line or is specifically a human fetal kidney cell line. Thus, the claimed invention encompasses detection of HEV-infected cells in culture and specifically encompasses detection of HEV- infected human fetal kidney cells *in vitro*.

The state of the prior art and the predictability or lack thereof in the art: The prior art teaches that HEV does not efficiently infect or replicate in cell lines *in vitro*. The prior art teaches that the only types of cells which have been found to support the replication of HEV *in vitro* are hepatocytes (see Reyes et al., Seminars in Liver Disease, 12(3):289-300, the paragraph bridging pages 90-291).

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The amount of direction or guidance present and the presence or absence of working examples:

The specification fails to disclose infection or replication of US-type HEV in human fetal kidney cells, or in any other cell lines in culture. There is a single working example (pages 104-105, Example 12) drawn to detection of HEV RNA in primary human fetal kidney cells. The art teaches that primary human fetal kidney cells are not considered to be a "cell line" per se, because they cannot be subcultured *in vitro* without loss of characteristic morphology and changes in viral susceptibility (see Schmidt, N.J., pp. 79-85 in Diagnostic Procedures for Viral and Rickettsial Infections, 4th ed., 1969, Lennette et al., ed., American Public Health Association, Inc.). Furthermore, the working example does not disclose HEV infection or replication in human fetal kidney cells and does not disclose detection of HEV in kidney cells. Rather, the specification discloses detection of US-type HEV RNA in a positive serum sample mixed with kidney cells, i.e., negative human kidney cells "spiked" with HEV US-2 positive serum (see page 104, lines 9-13).

The breadth of the claims and the quantity of experimentation needed: As set forth *supra*, the claims are drawn to detecting the presence of a US-type HEV in a mammalian cell line and specifically in a human fetal kidney cell line. The art teaches that HEV does not infect or replicate in mammalian cell lines other than human hepatocytes. The specification does not disclose a human fetal kidney cell line which supports infection and replication of US-type HEV and does not disclose detection of HEV in human fetal kidney or any other type of cells. Given the teachings of unpredictability in the prior art regarding HEV infection of cells other than hepatocytes and the lack of sufficient disclosure in the specification to overcome those teachings, one of skill in the art would be unable to practice the claimed invention commensurate in scope with the claims absent undue experimentation.

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Claim Rejections - 35 USC § 101

8. Claims 1-6, 12-15, and 24-26 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

This is a "written description" rejection.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A review of the language of the claim indicates that these claims are drawn to a genus comprising US-types or US-subtypes of HEV and naturally occurring variants thereof. A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). While applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus.

There are two species disclosed that are within the scope of the claimed genus, i.e. two isolates of US-type HEV. There is no disclosure of any of the variant species encompassed within the claimed genus. The disclosure of even a single species may provide an adequate written description of a genus when the species disclosed is representative of the genus. However, the present claim encompasses numerous species, i.e. naturally occurring variants, that are not described. There is no disclosure of any representative naturally occurring variants and no disclosure of any structural feature that is common to the variant members of the genus. Consequently, one skilled in the art would not recognize from the

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disclosure that the applicant was in possession of the genus of viruses which comprises US-types and subtypes of HEV and naturally occurring variants thereof. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

a. Claims 1-5 and 24 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. (Journal of Virological Methods, 38:175-186, 1992) in view of Schlauder et al. (IX Triennial International Symposium on Viral Hepatitis and Liver Disease, 04/1996; abstract A103) for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The claimed invention is drawn to a method of detecting the presence of a US-type or US-subtype HEV in a test sample comprising contacting the sample with a binding partner that binds specifically to a marker for the virus to form a complex and detecting the presence of the complex, wherein the marker is an IgG or IgM antibody and the binding partner is a polypeptide immobilized on a solid support. Although the presence of virus-specific antibody is not indicative of the presence of the virus itself in the sample, as was set forth *supra*, the claimed invention has been interpreted as drawn to a method for detection of virus specific antibody as indicative of exposure to or infection with a US-type HEV.

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Dawson et al. teach a method of detecting the presence of IgG and IgM antibodies directed against HEV comprising contacting a serum or plasma sample with an isolated polypeptide specific for HEV (see the Summary and page 177, first paragraph). Dawson et al. teach immobilizing the polypeptide on a solid support and detecting the antibody-polypeptide complex in a standard ELISA format (see page 178, first through fourth paragraphs). Dawson et al. differ from the claimed invention in that they describe HEV isolates from Mexico, Burma, Somalia, and Pakistan (see the abstract), rather than as a US-type or subtype.

Schlauder et al. teach identification of an isolate of HEV from an acute case of hepatitis E infection in the United States that is highly divergent from the Burmese and Mexican isolates. Schlauder et al. teach that the US HEV represents a third and unique group of HEV (see the last sentence of the abstract).

One of ordinary skill in the art at the time the invention was made would have found it *prima facie* obvious to have applied the method of testing for the presence of HEV specific IgG and IgM antibodies taught by Dawson et al. as a means of detecting infections due to or exposure to the US-type HEV disclosed by Schlauder et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do so for identification of one of the etiologic agents of hepatitis infection in the United States.

b. Claims 6, 12, and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. in view of Schlauder et al. 1996 and in light of Schlauder et al. (Journal of General Virology 79:447-456, March 1998; hereinafter Schlauder 1998) for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The claimed invention has been interpreted as drawn to a method of detecting the US-type or US-subtype HEV comprising contacting a test sample with a binding partner that binds specifically to a

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marker to form a complex and detecting the presence of the complex, wherein the marker is an antibody and the binding partner is a polypeptide consisting of SEQ ID NO:91 immobilized on a solid support.

As described *supra*, Dawson et al. teach a method of detecting HEV specific antibody comprising contacting a test sample with a polypeptide specific for HEV immobilized on a solid support so that an antigen/antibody complex is formed and detecting the presence of the complex in a standard ELISA. Schlauder 1996 teaches a US-type or US-subtype HEV. Neither Dawson et al. nor Schlauder 1996 teaches the polypeptide as consisting of SEQ ID NO:91.

Schlauder 1998 teaches a US variant of HEV which encodes the polypeptide of SEQ ID NO:96 (see Protein Sequence Search, database SPTREMBL, 05/30/2001, Result 1). Schlauder teach generation of synthetic polypeptides based on the US HEV sequence and development of ELISA for detection of IgG and IgM antibodies employing the synthetic polypeptides (see Schlauder 1998, the paragraph bridging pages 452-454). Finally, Schlauder 1998 teaches that epitopes of the US-type of HEV are diagnostically useful for identifying and distinguishing infections with US-type of HEV.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have employed the polypeptide antigen taught by Schlauder 1998 in the method disclosed by Dawson in view of Schlauder 1996, because Schlauder 1998 teaches that the polypeptide comprises diagnostically useful epitopes for identifying antibodies against the US-type of HEV.

c. Claim 25 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Dawson et al. in view of Schlauder 1996, as applied to claim 1 above, and further in view of Reyes et al. for the reasons outlined in the prior Office action (Paper # 10) and reiterated herein.

The claimed invention has been interpreted as drawn to a method of detecting the US-type or US-subtype HEV comprising contacting a test sample with a binding partner that binds specifically to a marker to form a complex and detecting the presence of the complex, wherein the test sample is a mammalian cell line.

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As previously described, Dawson et al. teach a method of detecting anti-HEV antibodies in a test sample comprising reacting the test sample with HEV-specific polypeptides for formation of an antigen/antibody complex and detection of the complex formed via standard ELISA. Schlauder 1996 teaches the U.S. type or US-subtype of HEV. Neither Dawson et al. nor Schlauder 1996 teach application of the ELISA for detection of viral antigens or polypeptides in a cell line.

Reyes et al. teach that HEV infects and replicates in mammalian hepatocytes and hepatocytic cell lines. Reyes et al. teach that development of an efficient *in vitro* culture system for hepatitis viruses is needed for virus propagation in order to facilitate biochemical analysis and ultimately vaccine formulation (see page 290, column 2, first full paragraph, through the paragraph bridging pages 290-291).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have used the ELISA test disclosed by Dawson et al. in view of Schlauder 1996 as a culture confirmation test for detection of virus propagation in an hepatocytic cell line. One of ordinary skill in the art at the time the invention was made would have been motivated to do so to facilitate analysis of the virus, for development of diagnostic antigens, and/or for formulating vaccine compositions.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Abbott (WO 95/02070) teaches a method of detecting the presence of anti-HEV antibody in a test sample comprising contacting the test sample with one or more synthetic peptides specific for HEV to produce an antibody/peptide complex and detecting the presence of the complex as indicative of the presence of the antibody in the test sample.

Schlauder et al. (Journal of Virological Methods 47:243-253, 1994) teach a method of detecting the presence of HEV RNA in a test sample by PCR.

11. No claims are allowed.

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12. This is a CPA of applicant's earlier Application No. 09/468,147. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Official FAX telephone number is (703) 872-9306 and the After Final FAX telephone number is (703) 872-9307. FAX machines will be available to receive transmissions 24 hours a day. In compliance with 1096 OG 30, the filing date accorded to each OFFICIAL fax transmission will be determined by the FAX machine's stamped date found on the last page of the transmission, unless that date is a Saturday, Sunday or Federal Holiday with the District of Columbia, in which case the OFFICIAL date of receipt will be the next business day.

Brenda Brumback
Brenda Brumback
Patent Examiner